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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/724,458

11/28/2003

Leslie William Organ

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LAHIVE & COCKFIELD, LLP  
ONE POST OFFICE SQUARE  
BOSTON, MA 02109-2127

EXAMINER

TOWA, RENE T

ART UNIT

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3736

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/724,458	<b>Applicant(s)</b> ORGAN ET AL.	
	<b>Examiner</b> RENE TOWA	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-14 and 16-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-14 and 16-24 is/are rejected.
- 7) ☒ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 5, 2008 has been entered.

2. This Office action is responsive to an amendment filed February 5, 2008. Claims 1-2, 4-14 and 16-24 are pending. Claims 1 & 13 have been amended. Claims 3 & 15 have been cancelled. No new claim has been added.

### ***Claim Objections***

3. Claims 6 & 18 are objected to because of the following informalities:

In regards to claim 6, the claim depends from cancelled claim 3.

In regards to claim 18, the claim depends from cancelled claim 15.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. **Claims 1-2, 7-11, 13-14, 19-23** are rejected under 35 U.S.C. 103(a) as being unpatentable over Organ (US 6,122,544) in view of Kueneck et al. (US 5,196,008) further in view of Newton et al. (US 4,416,276).

In regards to **claims 1 & 13**, Organ discloses a system for diagnosing the possibility of disease in a body part, the method comprising

- providing an electrode array containing a plurality of electrodes capable of being electrically coupled to the body part;
- making an electrode assessment measurement with the electrode array;
- making a diagnosis measurement with the electrode array;
- obtaining an electrical property of the body part based on the diagnosis measurement; and
- diagnosing the possibility of disease based on the electrical property of the body part (see fig. 5; column 3/lines 29-44; columns 4-11, lines 14-46).

In regards to **claims 2 & 14**, Organ discloses a system wherein the plurality of electrodes includes a current injection electrode pair and an associated voltage measurement electrode pair that are applied to the body part (see column 4, lines 35-39).

In regards to **claim 7**, Organ teaches a system wherein the plurality of electrodes includes  $n_{cl}$  current injection electrode pairs, and  $n_{cl}$  associated voltage measurement electrode pairs, where  $n_{cl}$  is an integer greater than zero (see Column 4, lines 35-38).

In regards to **claim 8**, Organ discloses a system wherein the step of making a diagnosis measurement includes applying the  $n_{cl}$  current injection electrode pairs on the body part; and applying the  $n_{cl}$  voltage measurement electrode pairs on the body part (see Column 4, lines 35-59).

In regards to **claims 9-11 & 19-23**, Organ discloses a system wherein the step of making a diagnosis measurement further includes

injecting a first current between a first pair of the  $n_{cl}$  current injection electrode pairs;

measuring the resultant voltage difference  $V_{sub.1.sup.M}$  between the voltage measurement electrode pair associated with the first current injection electrode pair; and repeating the preceding two steps of injecting and measuring with the other electrode pairs until all  $n_{cl}$  voltage differences,  $\{V_1^M, V_2^M, \dots V_{ncl}^M\}$  are obtained; wherein the electrical property is impedance; wherein the step of obtaining includes using the  $n_{cl}$  voltage differences to obtain associated measured impedances,  $\{Z_1^M, Z_2^M, \dots, Z_{ncl}^M\}$ , where  $Z_j^M$  is the measured impedance between the voltage electrodes associated with the  $j$ th current injection electrode pair (see Columns 6-8, lines 5-14; see columns 6-11, lines 5-53).

*Organ discloses a system, as described above, that fails to explicitly teach an electrode assessment measurement that includes a bipolar electrode assessment measurement that compares the measurement to anthropometric data indicative of adequate coupling.*

However, **Kuenecke et al.** disclose a system comprising:

providing an electrode array 1 (see fig. 1; col. 3, lines 22-31);

making a bipolar electrode assessment measurement with the electrode array 1 by utilizing one current injection electrode and one voltage measurement electrode (see col. 3, lines 40-50 & 58-68);

determining whether the plurality of electrodes (2-5) are suitably coupled to the body part based on a comparison of the bipolar electrode assessment measurement (see col. 4, lines 1-6 & 46-52; see abstract).

Moreover, **Newton et al.** disclose a system comprising:

coupling electrodes (20, 22) to a body part;

providing anthropometric data (i.e. an impedance value in a range of 20 to 144 ohms) indicative of adequate coupling between the electrodes (20, 22) and the body part (see col. 3, lines 33-62);

making a bipolar electrode assessment measurement by utilizing one current injection electrode 20 and one voltage measurement electrode 22 (see col. 3, lines 19-32);

determining whether the plurality of electrodes are suitably coupled to the body part based on a comparison of the bipolar electrode assessment measurement with anthropometric data (i.e. 20 to 144 ohms) indicative of adequate coupling between the electrodes and the body part (see figs. 1 & 4; col. 3, lines 33-62).

*In regards to **claims 1 & 13**, although Organ stresses the importance of good electrode/body contact (see col. 4, lines 49-54; col. 5, lines 54-58), Organ fails to teach an electrode assessment measurement to determine whether the electrodes are suitably coupled to a body part; however since both Organ and Kuenecke et al. teach systems comprising electrodes that are in contact with and apply electrical current through a body part, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify the system of Organ to include a bipolar*

*electrode assessment measurement as taught by Kuenecke et al. in order to determine whether the electrodes are suitably coupled to the body part; for example, poor electrode/body contact quality can lead to inconsistencies in measurement and diagnosis.*

*Similarly, although Organ teaches comparing the body impedances to anthropometric data indicative of disease state (see col. 3, lines 36-46; col. 9, lines 37-43; col. 10, lines 13-23 & 44-51; col. 11, lines 33-46), Organ fails to explicitly teach comparing the electrode assessment measurements to anthropometric data indicative of adequate coupling between the electrodes and the body part; however, since Newton et al. teach a system wherein the electrode assessment measurement is compared to anthropometric data in order to bind the electrode/body contact impedance between a lower and an upper limit threshold so as to thereby detect tenting, incorrect application site, gel drying and the hazards of applying the electrode on a surface other than the patient (see col. 3, lines 33-62), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Organ as modified by Kuenecke et al., above, with an anthropometric data comparison as taught by Newton et al. in order to bind the electrode/body contact impedance between a lower and an upper limit threshold so as to thereby detect tenting, incorrect application site, gel drying and the hazards of applying the electrode a surface other than the patient.*

6. **Claims 12 & 24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Organ ('544) in view of Kuenecke et al. ('008), Newton et al. ('276), and further in view of Dempsey et al (US 5,419,337).

*Organ as modified by Kuenecke et al. and Newton et al. discloses a system, as described above, that fails to explicitly teach a system comprising a GUI.*

However, Dempsey et al discloses a graphical user interface that indicates a status of the coupling between a plurality of electrodes and the body part (see col. 5, lines 13-29).

*Since both Organ and Dempsey et al. teach systems comprising electrodes that are in contact with a body part, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Organ to include a user interface, as taught by Dempsey et al, in order to interpret the quality of the signals of each electrode, for either gain selection or determining which electrodes may have poor skin contact.*

7. **Claims 4-5 & 16-17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Organ ('544) in view of Kuenecke et al. ('008), Newton et al. ('276), and further in view of Netherly et al. (US 6,171,304).

*Organ as modified by Kuenecke et al. and Newton et al. discloses a system, as described above, that fails to explicitly teach measuring a phase to determine suitable coupling of the electrodes to the body part.*

However, **Netherly et al.** disclose a system for determining whether the plurality of electrodes are suitably coupled to a patient body part through computation of a phase angle of the impedance (see col. 4, lines 32-36 & 45-50; col. 10, lines 43-49; see claims 1-4 of Netherly et al.).



*It is known that impedance includes both a magnitude and phase component. As such, Kuenecke et al. teach an electrode/body contact system that measures both the magnitude and phase of the electrode/body contact impedance (see col. 4, lines 46-52); Since Newton et al. disclose a method wherein electrode/body contact assessment is established by only monitoring the magnitude of the electrode/contact impedance with respect to anthropometric data (20 to 144 ohms) and since Netherly et al. teach that electrode/body contact assessment can also be established by only measuring the phase of the electrode/body contact impedance, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Organ as modified by Kuenecke et al. and Newton et al., above, with a phase determining step as taught by Netherly et al. in order to determine the quality of the electrode/body contact. Moreover, the Applicant has not disclosed that determining an impedance by way of a phase determination provides an advantage, is used for a particular purpose, or solves a stated problem over the prior art.*

8. **Claims 6 & 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Organ ('544) in view of Kuenecke et al. ('008), Newton et al. ('276), and further in view of Netherly et al. (US 6,007,532).

*Organ as modified by Kuenecke et al. and Newton et al. discloses a system, as described above, that fails to explicitly teach measuring a phase at a plurality of frequencies to determine suitable coupling of the electrodes to the body part.*

However, **Netherly et al.** disclose a system for determining whether the plurality of electrodes are suitably coupled to a patient body part through computation of a

magnitude and/or phase angle of the impedance; wherein the contact impedance at a plurality of frequencies serves as a means for determining the quality of electrode/body contact (see fig. 3; col. 3, lines 31-56; col. 4, lines 26-37 & 53-57; col. 5, lines 29-40).

*Since Newton et al. disclose a method wherein electrode/body contact assessment is established by only monitoring the magnitude of the electrode/contact impedance with respect to anthropometric data (20 to 144 ohms) and since Netherly et al. teach that electrode/body contact assessment can also be established by measuring the electrode/body contact impedance at a plurality of frequencies; it is known that impedance includes both a magnitude and phase component. Kuenecke et al. teach an electrode/body contact system that measures both the magnitude and phase of the electrode/body contact impedance (see col. 4, lines 46-52); as such, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Organ as modified by Kuenecke et al. and Newton et al., above, with an impedance at a plurality of frequencies as taught by Netherly et al. in order to determine the quality of the electrode/body contact. Moreover, the Applicant has not disclosed that determining an impedance by way of a phase determination provides an advantage, is used for a particular purpose, or solves a stated problem over the prior art.*

### **Response to Arguments**

9. Applicant's arguments filed February 5, 2008 have been considered but are moot in view of the new ground(s) of rejection.

### **Conclusion**

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information in regards to the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/R. T./  
Examiner, Art Unit 3736

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736